

REMARKS

Claims 1-36 are pending. Claims 1-36 stand presently rejected. Applicants have amended Claims 1-36, without prejudice. Support for the amendments to Independent Claims 1, 16, 25, 27, 33, and 35 can be found, for example, in Application paras. [0048, 0050-0051, 0053-0054], FIGS. 1-5, and throughout. Support for the amendments to Independent Claim 16 can also be found, for example, in Application para. [0078]. Support for the amendments to Independent Claim 27 can also be found, for example, in Application paras. [0046-0047]. Support for the amendments to Independent Claim 34 can be found, for example, in Application para. [0076]. Support for the amendments to dependent Claim 2 can be found, for example, in Application para. [0046, 0050, 0067] and FIG. 6. Support for the amendments to dependent Claim 3 can be found, for example, in Application para. [0049]. Support for the amendments to dependent Claims 4 and 20 can be found, for example, in Application paras. [0046, 0055] and FIG. 6. Support for the amendments to dependent Claims 5, 21, and 30 can be found, for example, in Application FIG. 7 and paras. [0057, 0076]. Support for the amendments to dependent Claim 6 can be found, for example, in Application paras. [0058, 0059] and FIG. 1. Support for the amendments to dependent Claim 7 can be found, for example, in Application para. [0050]. Support for the amendments to dependent Claims 8, 19, 22, and 29 can be found, for example, in Application paras. [0068-0070]. Support for the amendments to dependent Claim 9 can be found, for example, in Application paras. [0044, 0068-0072]. Support for the amendments to dependent Claims 10, 23, and 31 can be found, for example, in Application FIG. 6 and paras. [0015, 0076]. Support for the amendments to dependent Claims 11, 24, and 32 can be found, for example, in Application FIG. 7 and para. [0076]. Support for the amendments to dependent Claims 12, 13, 17, 18, 26, and 28 can be found, for example, in Application paras. [0044, 0061, 0068-0072], and throughout. Support for the amendments to dependent Claim 14 can be found, for example, in Application para. [0078] and in the claim itself. Support for the amendments to dependent Claim 15 can be found, for example, in Application paras. [0015, 0057-0058, 0060, 0076] and Fig. 2. Support for the amendments to dependent Claim 36 can be found, for example, in Application paras. [0055-0057, 0060, 0076]. Applicants submit that these

minor amendments and corrections herein are made without prejudice as to patentability, including the doctrine of equivalents, and no new matter has been added.

Applicants also submit a Declaration under Rule 1.132, attached hereto as Attachment A. Applicants further submit herewith a petition for a three-month extension of time and the required fee of \$555 for a small entity. The Commissioner is authorized to charge any additional fees or provide any refunds to the deposit account of Bracewell & Giuliani LLP, 50-0259 (Attorney Docket No. 0771CG.035249).

Rejection Under 35 USC §112, First Paragraph

Claim 2 was rejected as including subject matter that was not described in the original specification--reference to "duplicate therapies." Applicants respectfully point out that Application FIG. 13 includes a "duplicate therapies" table. Accordingly, Applicants respectfully submit that the claim element is supported by the original specification.

Rejection Under 35 USC §112, Second Paragraph

Claims 1, 5, 7, 12, 16, 21, and 26 were rejected as being indefinite for using the terminology "if." Although the Applicants respectfully disagree, Applicants have made appropriate amendments to remove such terminology.

Rejection Under 35 USC §101

Claims 1-26 were rejected as being directed to nonstatutory subject matter. Applicants note that the claims, as amended, satisfy both the machine and the transformation tests set forth in *Bilski* and set forth in the recently published "Subject Matter Eligibility Test for Process Claims."

Regarding the machine portion of the test with respect to Independent Claim 1, the claim features, for example, a computerized records (first) computer configured to manipulate and store the computerized records including the electronic medical record, and a correctional facility (second) computer configured to store computerized dispensation, receipt verification, and

administration verification records, which are both particular machines required to implement process steps of the claimed method. Notably, reviewing electronic medical records stored in the memory of first computer could not be considered a mere insignificant extra-solution activity, but rather, is an integral part of the claimed process performed by the computerized records computer, which requires use of the computerized records computer to perform the verification which is a prerequisite for the next "authorizing release" step and in the "labeling" step. Similarly, the compliance/consumption verification process of forming a record of dispensing a unit packet, forming a receipt verification record, and forming an administration verification record are integral parts of the process performed by the correctional facility computer, which impose meaningful limits on the claim's scope that are more than mere *insignificant* extra-solution activity. Accordingly, Applicants submit that the "machine" step of the test has been satisfied.

The "transformation" leg of the test is also satisfied. For example, from the review of the electronic medical records, the pharmacist can authorize release of the inmate's prescribed medication, which is inherently transformative as the prescribed medication was not yet released. Further, the process includes labeling a unit packet, which is another transformative step as an unlabeled unit packet would be transformed into a labeled unit packet. The next step involves delivery of the unit packet to a correctional facility, which is a spatially transformative step, as the location is being changed to that of a correctional facility. The next steps are also spatially transformative as they involve transferring the unit packet within a correctional facility unit and dispensing the unit packet. The next step of forming a receipt verification record in the memory of the correctional facility (second) computer responsive to the step of verifying receipt of the unit packet is also transformative (along with being tied to a particular machine) as it involves creation or amending of a record in response to an impetus. The second to last step of performing one of two available administration verification steps are transformative in that they involve forming an administration verification record responsive to the step of verifying whether or not the inmate consumed the prescribed medication. Finally, the last step of updating the inmate's electronic medical record is again a transformative process in that the electronic medical record is being transformed into an updated record.

As such, Applicants submit that multiple "articles" are being transformed and such *multiple transformations* involving both the computerized electronic medical record and electronic administration record documentation synergistically performed by the computerized records and correctional facility unit computers at *multiple computerized steps* clearly impose meaningful limits on the claims scope in accordance with *Benson*, which are more than a mere insignificant extra(post)-solution activity (which *Diehr*, fn. 14 defined as a "token" activity), more than a mere field of use limitation, and more than a mere use of a machine to collect data necessary for Application of a purely mental process. Accordingly, Applicants submit that such multiple levels of transformation embedded throughout the claimed process satisfy the transformation prong of the test in *Bilski*.

Correspondingly, Independent Claim 1 and corresponding dependent Claims 2-15 satisfy both legs of the subject matter eligibility test, and thus, are patentable subject matter. Independent Claims 16 and 25 along with dependent Claims 17-24 and 26 are also patentable subject matter under a similar line of reasoning.

Regarding Independent Claim 16, the claim features, for example, a pharmacy computer configured to manipulate and store the computer records, which is a particular machine required to implement process steps of the claimed method. Notably, displaying electronic medical records and correctional facility records, and later, [receiving] an authorization entered [in the computer] to update an inmate's electronic medical record are integral parts of the claimed process performed by the computer which require use of the computer to access and update (maintain) the electronic medical records and impose meaningful limits on the claim's scope that are more than mere *insignificant* extra-solution activity. For example, the review of the electronic medical record and the inmate's correctional facility record is a prerequisite from which the pharmacist can perform the step of verifying suitability of the prescribed medication (e.g., not only for the disease (from the review of the electronic medical record), but for the specific inmate based on prior inmate actions, whether the inmate is to be transferred, etc. (from the review of the inmate's correctional facility record)); and from the entry of the authorization to release the prescribed medication or the inmate, the inmate's electronic medical record is updated

(transformed). Accordingly, Applicants submit that the "machine" leg of the test has been satisfied.

The "transformation" leg of the test is also satisfied. For example, the step of entering an authorization into a pharmacy computer and updating an electronic medical record responsive thereto is transformative in nature as it results in an updated electronic medical record for the specific inmate; and the step of printing a label responsive to the authorization is also transformative in that it transforms a blank label to a printed label for a unit packet of the specific prescribe medication for the specific inmate. As the claim is directed to computerized monitoring of dispensation of pharmaceuticals to inmates in a correctional facility, such steps impose meaningful limits on the claim's scope and involve more than mere insignificant (token) extra-solution activities.

Correspondingly, Independent Claim 16 and corresponding dependent Claims 17-24 satisfy both legs of the subject matter eligibility test, and thus, are patentable subject matter.

Regarding Independent Claim 25, the claim, for example, features a [e.g., correctional facility] computer configured to manipulate and store dispensation, receipt verification, and administration verification records, which is a particular machine required to implement the process steps of the claimed method. Further, forming a record of dispensing a unit packet, forming a receipt verification record, and forming an administration verification record are integral parts of the process performed by the computer, and thus, impose meaningful limits on the claim's scope that are more than mere *insignificant* extra-solution activity. Accordingly, Applicants submit that the "machine" step of the test has been satisfied.

The "transformation" leg of the test is also satisfied. For example, the step of forming a receipt verification record in the memory of the computer responsive to the step of verifying receipt of the unit packet is transformative (along with being tied to a particular machine) as it involves the creation or amending of a record responsive to an impetus. The second to last step of performing one of two available administration verification steps is transformative in that they involve forming an administration verification record responsive to the step of verifying whether or not the inmate consumed the prescribed medication. Finally, the last step of providing a verification report is again a transformative process in that the report is provided

(transformed) based upon the administration verification record (impetus). As the claim is directed to computerized monitoring of dispensation of pharmaceuticals to inmates in a correctional facility, such steps impose meaningful limits on the claim's scope, and thus, involve more than mere insignificant (token) extra-solution activities.

Correspondingly, Independent Claim 25 and corresponding dependent Claim 26 satisfies both legs of the subject matter eligibility test, and thus, are patentable subject matter.

Rejection under 35 USC §103

Claims 1-36 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Chudy et al., U.S. Patent Publication No. 2004/0088187 (hereinafter "Chudy") in view of a Department of Health report entitled "A Pharmacy Service for Prisoners" (hereinafter "DOH"), and further in view of Hingoranee, U.S. Patent No. 7,278,028 (hereinafter "Hingoranee"). Applicants respectfully traverse the rejection.

The Present Application

Various embodiments of the present invention feature computerized systems, program storage media/program product, and methods which monitor/manage the inventory of pharmaceuticals and the dispensation of prescribed medication in conjunction with computerized records, for inmates. Such embodiments of the invention can beneficially make comprehensive electronic medical records visible to the pharmacist to allow the pharmacist to make decisions regarding the suitability of physician prescribed medications, beyond mere drug interactions. Further, such embodiments of the invention can beneficially also, or additionally, include provisions for a multistage electronic consumption documentation process which includes documenting actual dispensation, receipt, and verified consumption of a prescribed medication, and can include provisions for updating the electronic medical records and/or generating reports based upon whether the medication was consumed. Such features, and others, can serve to enhance/optimize the pharmacy management system for inmates from the origination of a medication order, to the actual delivery and consumption of the medication, to the documentation and reporting of such consumption.

The Cited Documents

The Chudy Patent

Chudy describes, for example, a system and methods for managing a pharmacy workflow associated with fulfillment of prescription orders for medications and health-related products in a pharmacy environment. Particularly, the system is described as sequencing prescriptions to minimize costs associated with filling of prescription orders, to minimize human involvement in the prescription order fulfillment process, to reduce the amount of time required to fulfill a prescription order, to reduce the spatial [(walking)] distance required to be traveled by pharmacy technicians to fulfill prescription orders, and to reduce the potential for errors in the fulfillment process.

Chudy, as a minimum, however, does not disclose, teach, or suggest a system or method which includes verifying suitability of a medication based on a medical record review in a combined automated and/or manual process directed to a relatively comprehensive electronic medical record, or forming a record in a computer indicating a verification of whether a patient actually took the prescribed medication, following a verification of receipt by the inmate of the medication. There are also many other differences discussed below.

The DOH Report

The DOH report by England's Department of Health sets out findings and recommendations supporting a desire/goal to integrate prison pharmacy services into England's national health services, along with an identification that 5-year funding has been allocated to fund future projects to realize the desire/goal. The DOH article, however, does not disclose the actual structure of functional systems, program product, or process steps. In fact, most, if not all of the recommendations provided in the report identify a shortfall in prison pharmacy services, without detailing the "hardware" to fix the shortfall.

The Hingoranee Patent

Hingoranee describes systems and methods for crosshatching biometrics with other identifying data. Hingoranee further describes that it is applicable for use in controlled environment facilities, such as a prison or jail. In a section describing various prison uses, Hingoranee makes note that inmates may be provided medical services, such as the dispensing of prescription medications, and that proper authentication of the inmate's identity would be desirable in such instance.

Hingoranee does not, however, disclose or teach the formation of a record indicating the dispensing of a medication, the formation of a record indicating receipt of the medication, or the formation of a record indicating whether or not a patient actually consumed the medicine.

Issues Addressed in the Response to Arguments Section

Applicants respectfully wish to first address issues raised in the "Response to Arguments" section of the Office Action prior to individually addressing the specific rejections of each claim (as amended). On an initial note, Applicants acknowledge that the Examiner is utilizing rationale (G), the teaching, suggestion, motivation test, with respect to presented obviousness rationale. Applicants also wish to thank the Examiner for indicating concerns regarding claim language being interpreted as being directed merely to an intended use. Applicants have made appropriate amendments, without prejudice, to satisfy the Examiner's concerns. Applicants also wish to thank the Examiner for indicating that the Examiner interpreted the claims to not include human interaction. Although Applicants believe that various aspects of certain elements of the claims necessarily indicated steps required to be performed by a human, Applicants have amended the claims, without prejudice, to positively claim human-machine interaction with one or more computers or articles of manufacture.

Regarding the issue of intended use, although Applicants have made appropriate claim amendments, some claim elements of some claims still may include language which can be interpreted as directed to an intended use. Regarding such language, Applicants respectfully submit that MPEP 2106(II)(C) does not indicate that "no patentable weight" should be given to

statements of intended use, but rather, indicates that a statement of intended use "may raise a question as to the limiting effect of the language in [the] claim." Notably, surrounding language may provide such claim elements with positive limitations. Additionally, statements such as, for example, verifying something as suitable for the [specific] inmate provides a specific limitation that that verified item is, or must be, suitable for the specific inmate and does not merely indicate the intended use of the verification-- i.e., the "for the inmate" language in such case, sets forth a specific limitation. Accordingly, such types of steps should be given patentable weight.

Regarding the issue of how Chudy defines verification, it is stated in the Office Action that "nowhere in the disclosure of Chudy does Chudy define verification as being defined as determining that the correct medication is in each medication [container]." Applicants respectfully submit that Chudy, para. [0082] at least inherently, if not explicitly, provides such definition as would be interpreted by one of ordinary skill in the art. Further, as to statement in the Office Action that "checking to ensure that the correct medication is in each container may be an essential step in the verification process but not the entire verification process," Chudy provides no other teaching as to what its verification process would otherwise entail, much less an enabling disclosure thereof beyond that which can be readily gleaned from the context--a verification that the medication intended to be in the medication container, is in fact, the medication in the container.

In this context, Applicants respectfully submit that verification of "suitability" is different than a verification that the right drug was put in the container. "Suitability" can include various factors to include not only suitability of the prescribed medication for the specific disease, but suitability for the specific inmate based on prior inmate actions, whether the inmate is to be transferred, etc. Although Independent Claim 1 does not specify specific details of what would be required in determining whether or not a medication would be suitable, it should be clear that merely verifying that the medication in a container is the medication listed in the prescription order would not be sufficient, as the medicine placed in the container may not be suitable, but may nevertheless, be verified as being the medicine listed in the prescription order.

Regarding arguments directed to the failure of the cited documents to recognize "the same problem or the source of the problem" as recognized by Applicants, Applicants wish to point out that although KSR, 82 USPQ.2d at 1397, may have indicated that Patent Examiner's need not *only* look to the problem the patentee was trying to solve, it is Applicants understanding that KSR, USPQ.2d 1397, limited the extent of the reach of such statement to "any need or problem known in the field of endeavor at the time of the invention *and* addressed by the Patent [or application at issue]" in order to "provide a reason for combining the elements in the manner claimed." See MPEP 2141.01(a)I (citing KSR International Co. v. Teleflex Inc., 550 U.S. _____, 82 USPQ2d 1385, 1397 (2007)) (emphasis added). Applicants merely pointed out that Chudy's problem related to human involvement in the prescription order fulfillment process and its solutions which were directed to minimizing such human involvement, were not problems addressed in the Application at issue to such an extent that Chudy's solution effectively teaches away from the direction in which the Applicants went--resulting in significant evidence that there would be no motivation to combine Chudy with other reference teachings to try to build the claimed embodiments of Applicants' invention.

As such, Applicants wish to point out that, even if the problems of Chudy were addressed in the Application, which Applicants contend there were not, the teaching away from the direction in which Applicants went by Chudy is highly relevant to a finding of a lack of motivation to combine reference teachings to try to somehow build the claimed embodiments of Applicants' invention. Further, regarding the statement that "the disclosure from the Department of Health [reference] specifically teaches a need for a pharmacy service system for prisoners," Applicants wish to point out that the general provision of pharmacy services to prisoners was not a problem which Applicants sought to solve, but rather, Applicants sought to address issues including proper inventory management, prisoner-specific aspects of medication suitability, and verification and documentation of medication administration, consumption, etc.

The References Do Not Teach All Claim Elements

Applicants respectfully submit that even if one were to ignore, for the sake of thoroughness, the lack of motivation to combine references, the lack of a reasonable expectation of success, or that Chudy teaches away from the direction to which the Applicants went, discussed in more detail in the prior Office Action Response and incorporated herein by reference, Applicants further respectfully submit that neither of the cited documents, alone nor in combination, teach all claim elements. Note, of Claims 1-36 rejected as being obvious under 35 U.S.C. § 103(a) as being unpatentable over Chudy in view of DOH and further in view of Hingorane, Claims 1, 16, 25, 27, 33, 34, and 35, are independent claims.

Regarding Independent Claim 1, as a minimum, neither Chudy, DOH, nor Hingorane, alone or in combination, disclose, teach, or suggest either a method which includes reviewing an electronic medical record (which is beyond the details of a mere prescription record), authorizing release of a prescribed medication verified as being suitable (e.g., based on a medical record review of the electronic medical record), or the unique consumption/compliance documentation procedures including the steps of forming a record of dispensing a unit packet of the inmate's prescribed medication to the inmate, forming a receipt verification record indicating verification that the inmate received the unit packet, and forming an administration verification record indicating a verification indicating an actual physical verification that the patient consumed/did not consume the medication. Note, one skilled in the art would understand that the claim is directed to outpatient medication delivery in correctional facilities and not delivery in a hospital environment or other closed medical system, which falls under a different set of rules and regulations.

The Office Action identifies that official notice was taken with respect to access to a patient's medical history, premising that "the patient's medical history [contained within an electronic medical record] is inherent since the pharmacist must determine what prescription has been approved for fulfillment and [of the prescription order] which requires a patient's medical history..." Applicants respectfully submit that only the "prescription order" is necessary, and thus, providing the pharmacist access to a patient's medical history would not be inherent. See

also Attachment A, paras. 4b3, and 4d2-4d6. Accordingly, Chudy does not disclose or teach reviewing an electronic medical record or authorizing release of a prescribed medication responsive to a verification that the medication is suitable based on the review of the electronic medical record.

The Office Action also identifies that the combination of Chudy and the DOH reference did not indicate the unique consumption/compliance documentation procedures of forming a record of dispensing a unit packet of the inmate's prescribed medication to the inmate, forming a receipt verification record indicating verification that the inmate received the unit packet, and forming an administration verification record indicating a verification indicating an actual physical verification that the patient consumed /did not consume the medication, but then premises that the Hingoranee, abstract, and col. 8, lines 31-58, provides such teaching. Applicants respectfully wish to point out that the cited passages, in contrast, describe an authentication/identification process which includes iterative and successive cross-hatching of biometric components with other identifying data to ensure proper authentication/identification of a person such as the proper authentication of an inmate when dispensing prescription medications. Applicants respectfully submit that performing a proper authentication (or identification) of a prisoner at a pill window prior to dispensing medication is not a teaching or enabling disclosure of the unique multiple-record formation consumption documentation process featured in the claim. See also Attachment A, para. 4d2. Accordingly, Hingoranee does not fill in the blanks missing by Chudy and DOH. Notably, as introduced, for example, in paras. [0059]-[0061] of the Application, such unique consumption documentation process featured in the claim can beneficially not only provide data to update an inmate's electronic medical record and/or computerized inmate record, but can produce data which can provide sufficient evidence to substantially reduce the number of grievances filed against the correctional facility claiming that the correctional facility did not providing adequate medical care.

Accordingly, Applicants respectfully submit that Independent Claim 1 has been shown to be allowable and define over the cited references. Applicants also submit that Independent Claims 25, 27, 33, and 35 are also nonobvious, at least for the reasons described above with

respect to the differences between the teachings of the cited references and the featured unique consumption documentation process.

Regarding Independent Claim 16, neither of the cited references teach the pharmacist performing a review of both a portion of the inmate's electronic medical record (including laboratory work results and medical checkup data) and the portion of the inmate's correctional facility record by a pharmacist to verify that the prescribed medication is suitable for the inmate, or updating an inmate's electronic medical record responsive to entry of an authorization releasing prescribed medication to the inmate into a pharmacy computer, as featured in the claim. Applicants respectfully submit that providing a pharmacist access to both electronic medical records (which can include doctor and nurse notes, vital signs, laboratory results, etc.) and correctional facility records (which can include information such as whether or not the inmate is transferring or due to be discharged, inmate propensities, etc.) is new and not an obvious variant of a conventional pharmacy procedures. See also Attachment A, paras. 4d4-4d6.

Regarding Independent Claim 34, neither of the cited references teach providing the pharmacist simultaneous access to both the inmates medical information (including laboratory work results and medical checkup data) and the inmate's prescription order, as part of a prescription approval. Applicants respectfully submit that providing a pharmacist access to both electronic medical records (which can include doctor and nurse notes, vital signs, laboratory results, etc.) is new and not an obvious variant of a conventional pharmacy procedures. See also Attachment A, paras. 4d4-d6. Additionally, neither of the cited references teach remotely (locally) caching in the pharmacy database each electronic medical record for each inmate contained within each prescribed medication shipment of a plurality of prescribed medication shipments scheduled to be shipped within a predefined time period prior to a pharmacist reviewing the respective inmate's electronic medical record and prescription order to prevent a potential disruption of medication delivery resulting from a breakdown in network communications between a pharmacy server/computer and a computerized records computer storing electronic medical records. Notably, this type of caching is in contrast to normal computer memory caching. Although individual records can be cached in memory during record

viewing and/or updating. Applicants submit that this is not equivalent to caching an entire batch to prevent a potential disruption in network communications. See Attachment A, para. 4d7.

Accordingly, Applicants respectfully submit that even if there were found to be a motivation to combine the teachings of the DOH report and/or Hingoranee with that of Chudy, the result would not fill in the missing elements described immediately above. Accordingly, Applicants respectfully submit that as neither of the cited documents, alone, nor in combination, disclose, teach, or suggest each and every element of Independent Claims 1, 16, 25, 27, 33, 34, and 35, the independent claims and their respective dependent claims (Claims 2-15, 17-24, 26, 28-32, and 36) have been shown to be allowable and define over the cited documents. Dependent Claims 2-15, 17-24, 26, 28-32, and 36, also are independently novel and nonobvious.

Claim 2, features, for example, at least in part, automatically reviewing the *electronic medical record* for drug-drug interactions[, duplicate therapies,] and allergies. Chudy, para. [0149] cited in the Office Action as providing such teaching, in contrast, describes a sequence sheet (bag) which provides detailed instructions for a patient taking the medication. Further, although it arguably may have been known to perform duplicate therapy or other checking based on dosing and dispensation records (medical administration records), as noted above, it was not known for a pharmacist to review an electronic medical record which can include all prescription orders even from other pharmacies--this was simply not available to the outpatient pharmacist at the time of the subject application. See Attachment A, para. 4d5. Accordingly, Applicants submit that Claim 2 has been shown to define over the cited documents and official notice.

Claim 3 (dependent upon Claim 2), features, for example, at least in part, also *manually* reviewing laboratory results, medical checkup data, and problems associated with an inmate contained within an electronic medical record prior to authorizing release of the prescribed medication. Chudy, para. [0082], cited in the Office Action as providing such teaching, in contrast, describes the pharmacist reviewing the prescription order at the filling/check workstation to ensure that the correct medication was placed in the correct container. Further, as noted above, as it was not known for a pharmacist to review an electronic medical record for

such information (see Attachment A, para. 4d7), Applicants submit that Claim 3 has been shown to define over the cited documents and official notice.

Claim 4, features, for example, at least in part, performing an automated comparison comparing the prescribed medication with a drug formulary of approved medication approved by the specific correctional facility unit housing the inmate. Chudy, paras. [0120]-[0121], cited in the Office Action as providing such teaching, in contrast, makes no mention of a drug formulary. Further, even assuming that it is somehow inherent for the sake of completeness, Applicants submit that providing individual correctional facility units its own drug formulary and performing an automated comparison for the specific inmate's prescribed medication is a new concept not disclosed or taught by the cited references. Accordingly, Applicants submit that Claim 4 has been shown to define over the cited documents.

Claim 5, features, for example, at least in part, preventing a potential disruption of medication administration resulting from a breakdown in network communications between the computerized records computer and the correctional facility unit computer located remotely therefrom by caching on the correctional facility unit computer at least portions of each electronic medical record for each inmate scheduled to receive prescribed medicines. As noted above, this type of caching is in contrast to normal computer memory caching. Although individual records can be cached in memory during record viewing and/or updating, Applicants submit that this is not equivalent to caching an entire batch to prevent a potential disruption in network communications. Accordingly, Applicants submit that Claim 5 has been shown to define over the cited documents.

Claim 6, features, for example, at least in part, verifying that the inmate is the inmate who has been prescribed the prescribed medication prior to forming a record in the computer of dispensing...responsive to an inmate swiping an identification card. Chudy, Fig. 28, cited in the Office Action as providing such teaching, in contrast, illustrates a computer screen showing prescription orders in a state where prior verification (verifying what was placed in the container) has not been undertaken. See Chudy, para. [0164]. Note, as identified previously, verification, according to Chudy, is defined as ensuring that the correct medication is in the correct container

(see para. [0082]), and not the identity of an inmate, or doing so as a prerequisite to creating a dispensing record.

Further, Claim 6 features, at least in part, receiving a data entry from a correctional facility pill window technician for the correctional facility unit indicating an allergic reaction to the inmate's prescribed medication, and updating the inmate's electronic medical record over a communications network responsive thereto, not disclosed, taught, or suggest by the cited references. Beneficially, allowing the entry at the pill window level rather than waiting for a physician appointment can enhance maintaining remotely located electronic medical records. Accordingly, Applicants submit that Claim 6 has been shown to define over the cited documents.

Claim 7, features, for example, at least in part, application of a correctional facility admissions computer in adding inmate enrollment data records to the electronic medical record when information related to a new inmate is not already present. Chudy, para. [0078], cited as providing such teaching, in contrast, describes entering prescription order information into a pharmacy computer. As noted previously, a prescription order would not be considered by one skilled in the art to be an inmate's paper medical record or an inmate's electronic medical record. Accordingly, Applicants submit that Claim 7 has been shown to define over the cited documents.

Claim 8, features, for example, at least in part, sorting each unit packet for each respective inmate into a shipment in accordance with a shipping schedule for delivery of the unit packets to each correctional facility after the prescribed medication has been labeled and prepared for shipment. Chudy, Fig. 7E and para. [0090], cited as providing such teaching, in contrast, describe dispensing by an automated dispensing machine shown in Fig. 5. No mention is made of sorting medication into a shipment in accordance with a shipping schedule. Accordingly, Applicants submit that Claim 8 has been shown to define over the cited documents.

Claim 9, features, for example, at least in part, performing an automated update of an inventory record of pharmaceuticals at the correctional facility. Chudy, paras. [0028]-[0029] and [0124]-[0132], cited as providing such teaching, in contrast, describe updating internal pharmacy inventory. Notably, Chudy makes no mention of tracking inventory for an institutional

customer. Accordingly, Applicants submit that Claim 9 has been shown to define over the cited documents.

Claim 10, features, for example, at least in part, preventing a potential disruption of medication delivery resulting from a breakdown in network communications between the computerized records computer storing inmate electronic medical records and a remote pharmacy computer located remotely therefrom by caching on the remote pharmacy computer each electronic medical record for each inmate contained within each shipment scheduled to be shipped within a predefined time period prior to the step of reviewing the inmate's electronic medical record. This type of caching is in contrast to normal computer memory caching. Although individual records can be cached in memory during record viewing and/or updating, Applicants submit that this is not equivalent to caching an entire batch to prevent a potential disruption in network communications. See Attachment A, para. 4d7. Accordingly, Applicants submit that Claim 10 has been shown to define over the cited documents and official notice.

Claim 11, features, for example, at least in part, preventing a potential disruption of medication delivery resulting from a breakdown in network communications between the computerized records computer storing inmate electronic medical records and a remote pharmacy computer located remotely therefrom by caching data related to each label to be printed for each shipment scheduled to be shipped within a predefined time period prior to printing the label. Chudy, para. [0030], cited as providing such teaching, in contrast, makes no mention of dealing with multiple shipments or delayed processing, but rather appears to describe printing in filling sequence. The caching is a feature provided by Applicants to prevent processing delays caused by network failure--a problem also not addressed by Chudy. As noted above, this type of caching is in contrast to normal computer memory caching. See Attachment A, para. 4d7. Accordingly, Applicants submit that Claim 11 has been shown to define over the cited documents and official notice.

Claim 12, features, for example, at least in part, procedures for reclaiming unused individual unit packets of, for example, a 30 day supply of unit packets--unconsumed items that remain sterile--which beneficially can enhance stock optimization and cost recovery. Chudy,

paras. [0033] and [0090], cited as providing a teaching of the locating step, and paras. [0117]-[0118] and [0153] cited as teaching the returning and adjusting inventory steps, in contrast, describe dispensing medication (the opposite of returning). Nothing is mentioned of locating and returning medication to a central pharmacy or adjusting the inventory in response to such returns. Accordingly, Applicants submit that Claim 12 has been shown to define over the cited documents and official notice.

Claim 13, features, for example, at least in part, performing an automated adjustment of an inventory record of pharmaceuticals for each inmate. Chudy, para. [0125], cited in the Office Action as providing such teaching, in contrast, describes tracking internal pharmacy inventory including dispensing machine inventory, but not the remote inventory of any institutional customers. Notably, due to the sheer volume of multiple unit doses of medication for multiple inmates in a correctional facility, prior to the teachings of the Application, management at the correctional facility unit level would have been difficult at best, if not impossible, for many correctional facilities. Accordingly, Applicants submit that Claim 13 has been shown to define over the cited documents.

Claim 14, features, for example, at least in part, automatically refilling the prescribed medication for chronic conditions once the step of reviewing a computerized inmate correctional facility record and the step of reviewing the inmate's electronic medical record to verify that the prescribed medication is suitable for the inmate, has been performed for the inmate's prescribed medication. Chudy, para. [0153] and official notice, cited as providing such teaching, in contrast, makes no mention of a capability of Chudy to bypass any of its process steps for subsequent refills. Applicants respectfully submit that Chudy is a workflow management system which requires adherence to its stated process steps. Further, merely having a capability of performing a refill is not a teaching of doing so only after a review of the inmate's correctional facility record and electronic medical record. A review of the correctional facility record, for example, can beneficially let the pharmacist know if the inmate is due to transfer or if there is some other issue which would warrant not performing the refill. Applicants note that the "if" terminology in the claim has been deleted. Accordingly, Applicants submit that Claim 14 has been shown to define over the cited documents and official notice.

Claim 15, features, for example, at least in part, scheduling a time period in which the prescribed medication is to be dispensed to the inmate. Chudy, para. [0149], cited in the Office Action as providing such teaching, in contrast, describes providing a recommended time of day that the medication should be *taken*, which would not be understood to be the same time that the medication is being *dispensed*. Further, Claim 15 features [locally] caching electronic medical records for each inmate within the correctional facility unit scheduled to receive prescribed medication during the scheduled time period response to the step of scheduling, and refusing to dispense prescribed medication to an inmate failing to match an identity of a scheduled inmate, not disclosed, taught, or suggested by either of the cited references. Accordingly, Applicants submit that Claim 15 has been shown to define over the cited documents.

The remaining dependent claims (Claims 17-24, 26, 28-32, and 36) which were not individually addressed in the Office Action, are also independently nonobvious. Claim 17 features, for example, delivering a multi-day supply of unit dose packets for each one of a plurality of different prescribed medications for each separate one of a plurality of inmates to a correctional facility unit that houses the inmates...; Claim 18 features, for example, performing an automated update of a correctional facility unit inventory record responsive to receipt of unit packets by the correctional facility unit; Claim 19 features, for example, sorting each unit packet of prescribed medication of a plurality of unit packets for each separate one of a plurality of inmates in a correctional facility unit in accordance with a shipment schedule...; Claim 20 features, for example, performing an automated comparison of the inmate's prescribed medication with a [correctional facility unique] drug formulary of approved medication for the individual correctional facility unit housing the inmate...; and Claim 21 features, for example, preventing a potential disruption of medication administration resulting from a breakdown in network communications between a computerized records computer and a correctional facility unit computer located remotely therefrom by caching at least portions of each electronic medical record for each inmate scheduled to receive prescribed medicines on the correctional facility unit computer.

Claim 22 features, for example, sorting each of a plurality of unit packets for each separate one of a plurality of inmates into a shipment...; Claim 23 features, for example,

preventing a potential disruption of medication delivery resulting from a breakdown in network communications between the pharmacy computer and the computerized records computer storing the electronic medical records and located remotely therefrom by caching each electronic medical record for each inmate contained within each shipment scheduled to be shipped within a predefined time period in memory of the pharmacy computer prior to the step of reviewing the inmate's electronic medical record; Claim 24 features, for example, preventing a potential disruption of medication delivery resulting from a breakdown in network communications between the pharmacy computer and the computerized records computer located remotely therefrom by caching data related to each label to be printed for each shipment scheduled to be shipped within a predefined time period in memory of the pharmacy computer prior to printing the label; Claim 26 features, for example, unique medication reclamation process steps directed to a 30 day supply of unit doses; and Claim 28 features, for example, scheduling shipping of each of a plurality of unit packets for each of a plurality of different prescribed medications for each separate one of a plurality of inmates... and performing an automated update of a pharmaceutical inventory record based upon receipt of the unit packets by the correctional facility unit.

Claim 29 features, for example, sorting each unit packet of the plurality of unit packets for each separate one of a plurality of inmates in the correctional facility unit into a shipment...; Claim 30 features, for example, preventing a potential disruption of medication administration resulting from a breakdown in network communications between a computerized records computer storing the inmate's electronic medical record and a local correctional facility unit computer located remotely therefrom by caching in memory of the correctional facility unit computer at least portions of the electronic medical record for each inmate scheduled to receive prescribed medicines; and

Claim 31 features, for example, preventing a potential disruption of medication delivery resulting from a breakdown in network communications between a pharmacy computer and a remote computerized records computer storing electronic medical records and located remotely therefrom by caching in memory of the pharmacy computer each electronic medical record for each inmate contained within each shipment scheduled to be shipped within a predefined time

period prior to the step of reviewing the inmate's electronic medical record; Claim 32 similarly features, for example, preventing a potential disruption of medication delivery resulting from a breakdown in network communications between a pharmacy computer and a remote computerized records computer storing electronic medical records and located remotely therefrom by caching in memory of the pharmacy computer data related to each label to be printed for each shipment scheduled to be shipped within a predefined time period prior to printing the label; and Claim 36 features, for example, a medication dispensation workstation is further configured to display a medical compliance/consumption or a medical administration record for the inmate [to a pill window technician].

Summary

Applicants respectfully submit that a prima facie case of obviousness has not been established. The primary reference, at least inherently, teaches away from the direction to which the Applicants went. As such, there is no motivation to combine reference teachings. Further, even if there were found to be a motivation to combine reference teachings, due to missing elements there would be no expectation of success in combining the teachings in order to build the claimed embodiments of the Applicants invention. Still further, the cited references, alone or in combination, do not teach each and every claim element. Additionally, even if it were determined that a prima facie case of either anticipation or obviousness was established, Applicants submit that Applicants have submitted sufficient evidence to rebut such a showing.

In commenting upon the references and in order to facilitate a better understanding of the differences that are expressed in the claims, certain details of distinction between the references and the present invention have been mentioned, even though such differences do not appear in all of the claims. It is not intended by mentioning any such unclaimed distinctions or making any amendments herein to create any implied limitations in the claims. Not all of the distinctions between the cited patent documents and claimed embodiments of Applicants' present invention have been made by Applicants. For the foregoing reasons, Applicants reserve the right to submit

additional evidence showing the distinctions between the claimed embodiments of Applicants' invention to be novel and nonobvious in view of the cited patent documents.

The foregoing remarks are intended to assist the Examiner in re-examining the application and in the course of explanation may employ shortened or more specific or variant descriptions of some of the claim language. Such descriptions are not intended to limit the scope of the claims; the actual claim language should be considered in each case. Furthermore, the remarks are not to be considered to be exhaustive of the facets of the invention that render it patentable, being only examples of certain advantageous features and differences.

CONCLUSION

In view of the above remarks, Applicants submit that the Application is in condition for allowance. As such, the issuance of a Notice of Allowance is respectfully requested.

Respectfully submitted,

Date: October 2, 2009

/Denver S. Bisignano/
Denver S. Bisignano
Registration No. 60,693
BRACEWELL & GIULIANI LLP
P.O. Box 61389
Houston, Texas 77208-1389
Voice: (713) 221-1491;
Fax: (713) 437-5346